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10 July 2005

SOMAR TECHNOLOGIES LIMITED
INTERNATIONAL PATENT APPLICATIONS
PCT/US05/08136
PCT/US05/08138
PCT/US05/08010

Your Ref:

Our Ref: WEJ504795, 504796 and 504797

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Wes Jones – Partner
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Diane Varnam – PA/Team Administrator

CONFIRMATION

We **enclose** certified copies of the priority documents for these applications.

Yours faithfully
Baldwins

Wes Jones
Partner

WEJ:WEJ:010PA4420052

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PCT/US05/08010

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 10 March 2004 with an application for Letters Patent number 531705 made by SOMAR TECHNOLOGIES LIMITED.

Dated 8 July 2005

Neville Harris
Commissioner of Patents, Trade Marks and Designs

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531705

Patents Form No. 4 Our Ref: WEJ504797

Patents Act 1953

PROVISIONAL SPECIFICATION

ORTHOTIC DEVICE

We, **SOMAR TECHNOLOGIES LIMITED,** a New Zealand company, of Level 27, 151 Queen Street, Auckland, New Zealand do hereby declare this invention to be described in the following statement:

PT043966413

Orthotic Device

Field of the invention

This invention relates to orthotic devices, and his particular application to the interface between the device and the body of a user of the device.

Background

Orthotic devices generally include a substantially rigid "biomechanical" element which forms the basis of the skeletal support that is required for the majority of these devices which include braces, supports and splints.

In order to affix the device to the body of a user, the rigid element will usually include some form of liner which contacts the body of the user. The liner is usually constructed of a relatively soft, flexible or elastic material such as a foam material, and may have an outer fabric which is designed to contact the skin of a user directly, or alternatively to engage with clothing that a user may be wearing about the part of the anatomy to which the device is to be attached.

A problem with orthotic devices is that they must engage effectively with soft tissue in order to provide the desired support. In many parts of the body the soft tissue will move, for example by expanding or contracting as result of muscle movement. As a soft tissue changes shape, parts of the skin lose contact with the liner of the orthotic device. This reduced contact with the liner can cause the orthotic device to lose position, or move relative to the user and therefore become ineffective. The only way of overcoming this problem with existing devices is to tighten the device. This causes discomfort, prevents the skin from breathing, and can irritate the skin about the edges of the device and the liner.

With the current art if a mobile piece of soft tissue such as muscle displaces the portion of the liner adjacent to it, it will destabilise the entire liner as it is one piece. A one piece liner covering variably mobile bits of soft tissue reduces the stability of the brace and therefore the consistency of the force applied to the underlying skeleton.

Object

It is an object of the present invention to provide an orthotic device, or apparatus for such

a device, which will at least go some way toward overcoming disadvantages of existing constructions, or which will least provide the public with a useful alternative.

Summary of the invention

Accordingly in one expect the invention broadly provides an orthotic device having a substantially rigid support and a liner means for provision between the support and the body of a user, the liner means comprising a plurality of spaced protruberances.

Preferably each protruberance comprises a distinct element attached directly or indirectly to the support.

Alternatively some or all of the protruberances are interconnected and together attached directly or indirectly to the support.

Preferably each protruberance comprises a segment or series of segments which may be individually connected or disconnected (either directly or indirectly) to or from the support.

Preferably each segment comprises a material having properties of resilience covered with a sheet material. Preferably the sheet material comprises a material that has wicking properties. This reduces moisture accumulation which leads to slippage and irritation. Protruberances allow airflow as well which reduces moisture accumulation.

Preferably the material comprises a material such as that sold under the trade mark DRYX.

Preferably the segments are arranged depended upon the anatomy about which the orthotic device is to the fixed.

Preferably selected properties of each segment may be selected by a user to improve engagement of the orthotic device with the anatomy of the user, such properties including without limitation shape, size and resilience.

Preferably the segments may contain or include materials such as solid pockets (for example air or water) or gel.

Alternatively to addition, the segments may include means to provide electrophysical

modality such as muscle stimulation or TENS.

Preferably each, or selected, segments may include one or more electrodes for providing electrophysical modality.

Further respect to the invention will become apparent from the following description, which is given by way of example only.

Drawing description

We are more embodiments of the invention will be described below with reference to the company drawings, in which:

Figure 1 is a front elevation of a knee brace

Figure 2 is a rear elevation of the brace of Figure 1

Figure 3 is a partial plan view of the brace of Figures 1 and 2

Figures 4 and 4A are a plan view and side elevation of a liner element

Figures 5 and 5A are a plan view and side elevation of another liner element

Figure 6 is a front elevation and rear elevation of a liner segment having electrophysical modality.

Detailed description

The invention will be described with reference to a knee brace, however it will be understood that the invention is also applicable to other orthotic devices.

Referring to figure 1, a knee brace is shown having a biomechanical support comprising two substantially rigid arms 2 and 3 which are joined together by a hinge assembly 4. Connected to the arms are upper and lower structures 6 and 8 respectively which, together with straps 10 and 12 are used to form a primary engagement with the user's leg above and below the knee. This engagement can be augmented by further straps 14 and

16. The hinge assembly 4 has a predetermined range of movement corresponding to the desired range of flexion -- extension of the knee of the user.

In the preferred embodiments, support structures 6 and 8 comprises adaptive members that are constructed from a semi-rigid material such as a thermoplastic elastomer or a thermoplastic rubber. The selected material preferably has one or more of the following properties:

Hardness	2-45 (Shore A)
Specific Gravity	0.85-0.95 (gm/cubic cm)
Tensile Strength	5-60 (kg/square cm)
Elongation at Break	1100-650 (%)
Tear Strength	30-50 (kg/square cm)
Brittle Temperature	minus 30 – minus 60 (degrees C)

Furthermore, the preferred embodiments may include a rigid material 18 that is integrally moulded into structures 6 and 8, or is alternatively fixedly attached to the structures. Material 18 has a greater rigidity than the semi-rigid material from which structures 6 and 8 are moulded, and is preferably malleable. In the preferred embodiments, material 18 comprises a sheet aluminium material which has an appropriate thickness (for example one millimetre to two millimetres thick) so that it may be shaped by user using his or her hands to assist the adaptive material from which structures 6 and 8 are manufactured to conform to the part of the anatomy to which the device is to be attached.

Attached directly or indirectly to the structures 6 and 8 is a liner means. This may take a variety of different forms. In the most preferred embodiments illustrated in the drawing figures, the liner means takes the form of a number of discreet segments referenced 20.

Each segment 20 preferably comprises a resilient material which may be formed by moulding for example, cutting or otherwise shaping an appropriate material. Alternatively, and the most preferred embodiments, each segment 20 comprises a material such as a soft resilient foam and an outer layer of material which is intended to contact human skin and has wicking properties, such as material sold on the trademark DRYX.

Each segment 20 may also have properties of resilience provided by a fluid, such as air or

water, or other substances such as gels.

The segments may be engaged with support structures 6 and 8 by providing those structures with a selected lining, such as a hook and loop material, for example that sold under the trade mark VELCRO. Corresponding hook and loop material provided on the rear portion of each segment can then be engaged with that on support structures 6 and 8 so that the segments are provided in the desired position. This construction has a further advantage that the segments may be repositioned depending upon the requirements of the user. Furthermore, and segments of a number of different shapes and sizes having different properties (for example varying properties of resilience or hardness) may be provided and the user may substitute varying segments or rearrange the location of segments so that a comfortable and effective fit is achieved.

There are two elements to this. Interchangeable segments allow an enhanced degree of customisation for individual soft tisse fit in terms of filling defects or absorbing protruberances. A second factor relates to tissue turgor or density. If the liner is interfaced with loose or fatty tissue then it needs to be denser to maintain grip. If it is over hard mobile muscle it is advantageous to have a more absorbive less dense segment so that the muscle movement is better absorbed and the brace less destabilised by the soft tissue movement. So the segments provide two further levels of individual customisation with respect to interfacing rigid elements with soft tissue in order to impart a predictable force on the underlying skeleton.

As another alternative, the segments may advantageously be linked together. For example, in figures 4 and 5 segments 20 are illustrated being interconnected by being placed on a substantially planar substrate 24. As can be seen, each segment 22 protrudes, so that when a rear surface of substrate 24 is affixed to support 6 or 8 for example, the segments may contact with the body of the user. As discussed above, segments 22 may also be provided with varying properties, for example varying size (including varying height of protrusion), varying properties of resilience or support, and varying position.

The design of the segments can also be such as to facilitate skeletal grip, quite apart from grip to soft flesh or pure arrangement for user comfort. Therefore, for example the interconnected segments illustrated in figures 4 and 5 may be provided in a knee brace to provide skeletal grip.

Knee braces are generally designed to exert a force on the tibia. The central hinge provides a central axis, the femoral or thigh portion provides a lever arm and a means of stabilising the central axis, and the tibial portion imparts a force on the tibia or lower leg. If someone has an anterior cruciate deficient knee (an ACL injury) ACL bracing may be required. In ACL bracing the object is to hold the tibia back or prevent it form subuxing forward and then rotating. It is undesirable because it traumatises the cartilege. Now the skeleton is very close to the surface along the front or anterior border of the tibia. It is desirable to get a grip on the skeleton as that what braces attempt to control. The segments referred to in Figures 4 and 5 grip the anterior border much better than a flat segment across it would. Variably shaped segments for this specific area may also be provided so as to customise the grip further for any given individual.

Turning to figure 6, yet another application of the invention can be described with reference to segment 26 which on reverse side can include an attachment such as a region of Velcro 28 to enable segment to be connected to the support structure of the orthotic device, as described above. However, on the side of the segment that contacts the body of the user, the segment includes one or more electrodes 30 which are supplied with electrical energy by one or more conductors 32. By supplying electrical energy in the desired form, the segment 26 can provide Electrophysical Modality such as muscle stimulation, for example stimulating quadriceps muscles in knee braces, and all provide pain relief such as they commonly known as TENS. Each segment (or selected segments) may include one electrode which forms a circuit with another electrode (or electrodes) on other segments.

In another embodiment recesses may be placed in the contact surface so as to apply a skin dressing to a particular area. The dressing could be just that of a specific medicated application for an ulcer such as is commonly the case with diabetics.

It will be seen that when the protruberances are linked they still act independently as the connecting pieces are mobile and do not transmit force or movement from one segment to the other. The linkage is for convenience and ease of handling when washing etc.

As can be seen from the foregoing, the invention provides a lining means for an orthotic

device which includes functional segments that provide a number of different advantages.

One advantage is grip, both in terms of gripping the soft tissue of the user in to enable the device to function effectively, and also to be able to provide skeletal grip in some situations where this may be advantageous.

The invention has advantages in relation to skin, the skincare and general,fit. Since each segment is raised, there are spaces between segments and this allows air to circulate. General fit is improved because the segments allow variations such as prominent as in the contour of the user's body to be accommodated. Furthermore, because the segments effectively provide a noncontinuous surface to the skin of a user, movement of soft tissue, such as muscle, adjacent to one segment is less likely to affect the contact of another segment with the body of the user. Accordingly, a more secure, it is achieved.

Another advantage is the Electrophysical Modality described above.

Yet another advantage is that the segments tend to keep the support structure, or least edges of the support structure, away from the user's skin. This assists in reducing irritation.

Where in the foregoing description, reference has been made to specific components or integers of the invention having known equivalents then such equivalents are herein incorporated as if individually set forth.

Although this invention has been described by way of example and with reference to possible embodiments thereof, it is to be understood that modifications or improvements may be made thereto without departing from the scope or spirit of the invention.

It should be noted that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is, therefore, intended that such changes and modifications be included within the present invention.

3 March 2004

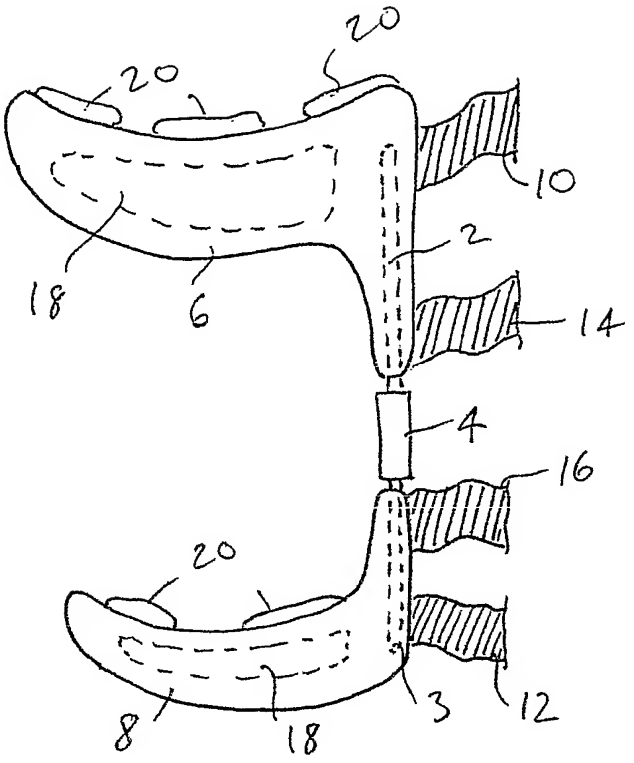


FIG 1

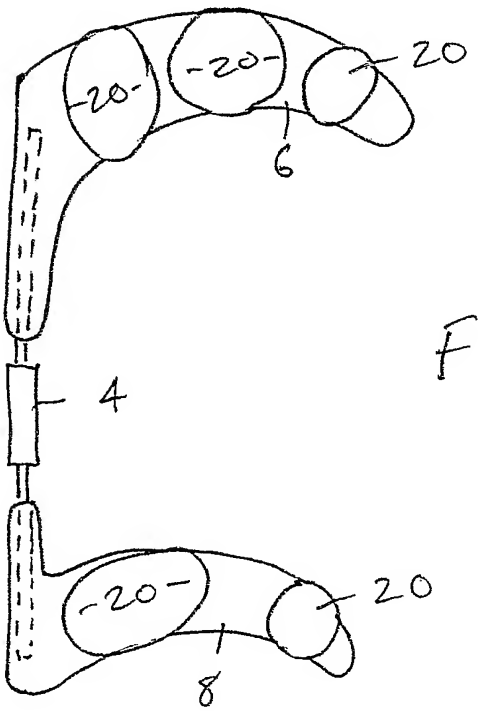


FIG 2

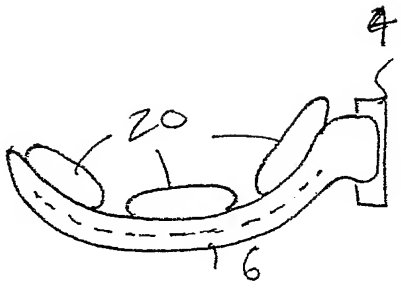
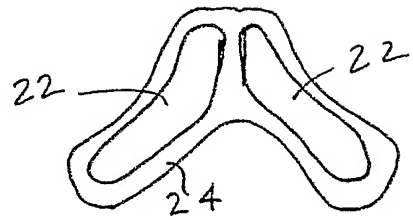


FIG 3

FIG 4A



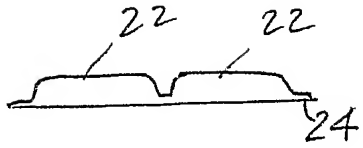
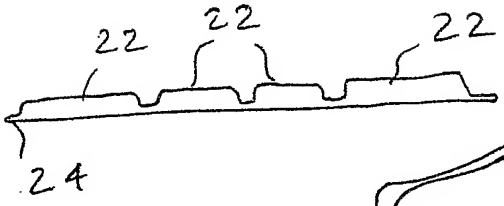


FIG 4

FIG 5A



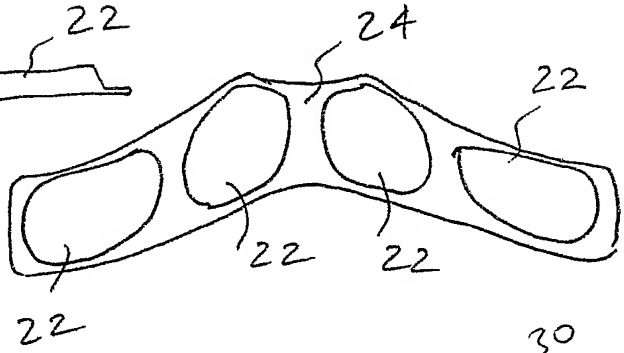


FIG 5

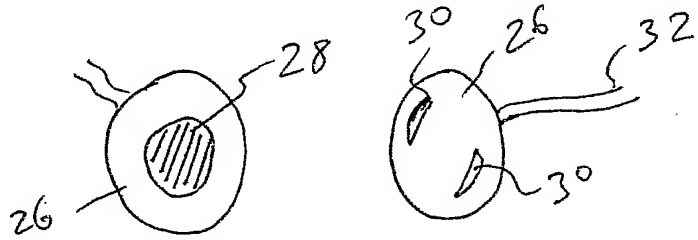


FIG 6